

# **EXHIBIT F**

## MORTALITY PATTERNS AMONG MINERS AND MILLERS OF NON-ASBESTIFORM TALC: PRELIMINARY REPORT<sup>1</sup>

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*A two-phase study, consisting of both mortality and environmental assessments of workers exposed to talc free of asbestos and of significant quantities of free silica, was undertaken. This population was drawn from Vermont Health Department records of employees of five companies in three geographic locations; three of these, located in two of the three geographic areas, are currently in operation. Mortality patterns in these talc workers were assessed from January 1, 1940 through December 31, 1975 and cause-specific expected numbers of deaths calculated from white male rates for the United States and Vermont, using a modified life table technique.*

*Excess non-malignant respiratory disease mortality was observed in millers, a group thought to have greater lifetime dust exposures than miners. No such excess was observed among miners. Excess lung cancer mortality was observed in the miners, but expected deaths are small and exposures other than talc are suspect for this excess.*

*It was not uncommon for past exposure levels of talc to far exceed the present Occupational Safety and Health Administration and the Mining Enforcement and Safety Administration Standard of 20 mppcf for nonfibrous talc (<1 percent free SiO<sub>2</sub>).*

*Analyses of both current airborne dust samples and talc bulk samples showed talcs from all locations in the currently operating mines and mills studied to be similar in composition. No asbestos was detected in any of the samples analyzed by either x-ray diffraction or analytical electron microscopy. Levels of free silica in bulk samples were below 0.25 percent for nearly all samples.*

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and only in occasional air samples was free silica detectable. Talc shards and ribbons were seen in talc bulk and airborne dust samples. In addition to the mineral "talc," other minerals present in these ores in significant quantities include magnesite, chlorite, and dolomite in addition to traces of calcite, biotite, ankerite, and phlogopite.<sup>4</sup>

To determine potential differences in the talcs mined and milled by the company (in the third geographic location) no longer in operation, seven samples of talcs were obtained and analyzed by the same techniques mentioned above. These samples were found to be free of asbestos contamination and to have a mineral composition within the range of samples from currently producing operations. The remaining company (also, no longer in operation) was located in the same geographic area as two of the currently operating companies.

## INTRODUCTION

Industrial and consumer applications of talc and associated minerals are widespread. Talc is used in such industrial applications as fillers in asphalt, paper, rubber, ceramics, paints, and plastics. Also, uses include various dusting applications to prevent adhesion, and use as a parting agent in molding operations. Consumer applications include its use as a filler for pills and tablets, as a cosmetic talcum, and in some countries as a coating for polished rice (Blejer and Arlom, 1973; U.S. Bureau of Mines, 1975).

A dichotomy has been identified in the classification of "talc": asbestiform "talc," including anthophyllite, tremolite, and/or chrysotile, and non-asbestiform talc. Early studies do not recognize this dichotomy and the potential for differing health effects. The first reported case of "talc" pneumoconiosis was described by Thorel in 1896.

Since then, studies of asbestiform talcs have repeatedly shown their association with progressive pneumoconiosis, both among miners and millers (Dreesen and Della Valle, 1935; Porro et al., 1942; Siegal et al., 1943; Kleinfeld et al., 1955). An increased risk of respiratory tract cancer among miners and millers exposed to talc containing anthophyllite and/or tremolite has also been demonstrated (Kleinfeld et al., 1967, 1974).

Until only recently there has been a paucity of epidemiologic data about workers exposed to talc free of both asbestiform minerals and significant quantities of free crystalline silica. Studies of industrial populations exposed to these talcs present conflicting results. In Italy, workers exposed to such talcs, during both its extraction and its industrial use, demonstrated a pneumoconiosis, diagnosed by roentgenographic evidence, that was reported to affect neither respiratory function nor working capacity (Maranzana et al., 1963; Scansetti et al., 1963a,b). Subsequently a mortality study by Rubino et

<sup>4</sup>Analyses presented in Boundy, M.: Occupational Exposure to Non-Asbestiform Talc in Vermont. Presented at Conference on Occupational Exposure to Fibrous and Particulate Dust and Their Extension into the Environment, Washington, D.C., December 6, 1977.

*al.* (1976) found that miners exposed to similar ores demonstrated an increased risk of pneumoconiosis mortality, which the authors attributed to exposure to crystalline silica. However, Fine *et al.* (1976), in a cross-sectional study of rubber workers performing dusting operations with talc low in asbestos fiber and free silica content, demonstrated progressive decrements in pulmonary function associated with increasing duration and magnitude of exposure, after controlling for factors known to affect pulmonary function. Other authors had previously suggested such a possibility based on case reports only (Millman, 1947; Seeler *et al.*, 1959).

As a result of unanswered questions concerning the toxicity of talc free of both asbestiform minerals and significant quantities of free silica, the National Institute for Occupational Safety and Health undertook an industry-wide study (cohort mortality study, industrial hygiene study, and cross-sectional medical examination) of Vermont talcs meeting these criteria (i.e. low free silica and no asbestiform minerals). This report contains an assessment of mortality patterns among the cohort exposed to this talc.

## MORTALITY STUDY

### Materials and Methods

Selected for study were all male Caucasian talc workers who had been radiographed as part of the Vermont Health Department's annual surveys, initiated in 1937, of workers in the dusty trades. Out of this group, workers who met the following criteria were included in the study cohort: 1) workers were included who were employed in the Vermont talc industry between January 1, 1940 and December 31, 1969; and 2) workers had been employed a minimum of one year before December 31, 1969. Five companies in three geographic areas were studied; two of these companies ceased operations in 1952 and 1960. Follow-up of all study group members, therefore, was from the time of the initial radiographic examination as a talc worker, the date when twelve months of employment was achieved, or January 1, 1940, whichever was later; and was continued through December 31, 1975.

Occupational and demographic data were obtained from the survey records of the Health Department and the companies to permit vital status follow-up. Company records were only used to supplement Health Department work histories when the latter were found to be incomplete.

Vital status ascertainment of the members of the study cohort was determined through December 31, 1975 by means of records maintained by federal, state, and local agencies. This included sources such as the Social Security Administration, state vital statistics offices, and state motor vehicle registration files. For individuals not located through these data sources, other data sources, such as city directories, post office mailing correction services, and other local records were used.

As a result of this follow-up program, only 1.0 percent (Table 1) of the study cohort (4 of 392 workers) was lost to observation. Death certificates were obtained from state vital records offices for those known to be dead.

and causes of death were interpreted and classified by a qualified nosologist, according to the Revision of the International Lists of Disease and Causes of Death in effect at the time of death. These codes were subsequently converted to the 7th Revision.

For analysis, the total study cohort was examined and later was classified into two work areas: milling (225 workers) and mining (163 workers). The worker was required to have a minimum of one year exposure in the area to qualify for inclusion. These two groups were not mutually exclusive. Forty-seven workers (12 percent of the total population) qualified for inclusion in both groups.

TABLE 1. Vermont Talc Study Cohort Status as of December 31, 1975

	Study Cohort Members	
	No.	%
Known to be alive	298	76.0
Known to be deceased	90	23.0
Death Certificate obtained	85	21.7
Death Certificate outstanding	5	1.3
Not known to be alive or deceased	4	1.0
	392	100.0

A modified life table technique was used to obtain person-years of observation by 5-year calendar time periods, 5-year age groups, 5-year exposure groups, and 5-year latency groups. Latency is the number of years since onset of initial employment. Comparison was made between the observed number of deaths in the study cohort and the number expected on the basis of sex, age, race, calendar time, and cause-specific mortality rates. Since many occupational cohort mortality studies have used U.S. rates for comparison, this group was used in this study. However, Vermont rates for the causes of death of interest in this study, non-malignant respiratory disease and respiratory cancer deaths, are greater than the U.S. rates. Therefore, comparisons were made for these causes of deaths with those expected using Vermont rates. Cause-specific expected deaths for the study population were obtained by applying death rates, calculated from yearly tallies of deaths and census data, to the person-years of observation of the cohort members. The yearly deaths for the U.S. from 1940 to 1967 were obtained from the yearly *Vital Statistics of the United States*, National Center for Health Statistics. After 1967, deaths were estimated using a linear extrapolation for all causes of death. The Vermont death data were obtained for

all years from 1949 through 1975 from the Vermont Office of Vital Statistics. U.S. and Vermont population estimates were obtained from the decennial data of the Bureau of Census, U.S. Department of Commerce. The mid-points of the five-year calendar periods were estimated using linear interpolation.

Statistical significance (2-tailed) was determined using "Confidence Limits for the Expectation of a Poisson Variable" (Pearson *et al.*, 1958).

In addition to the preceding analyses, other relevant data were examined: the most recent radiograph taken for the Vermont Health Department annual surveys was obtained for workers dying of non-malignant respiratory disease and read for pneumoconiosis by a member of the panel of radiology consultants of NIOSH, using the UICC/Cincinnati classification of radiographic appearance of pneumoconiosis. These radiographs (14" by 17") were read blind, that is, with no knowledge of exposure to talc or the underlying cause of death. Readings of 1/0 or higher were considered consistent with pneumoconiosis.

TABLE 2. Number of Expected and Observed Deaths by Cause Among Vermont Talc Workers, 1940 Through 1975

Cause of Death (ICD No., 7th Revision)	Observed	Expected US <sup>a</sup>
Heart Disease (400-443)	29	32.92
All Malignant Neoplasms (140-199)	16	12.79
Respiratory (160-164)	6	3.69
Total Non-Malignant Respiratory Disease (470-527)	11 <sup>b</sup>	3.67
Influenza and pneumonia (480-493)	0	1.89
Other Non-Malignant Respiratory Disease (470-475, 500-527)	11 <sup>b</sup>	1.79
Other Known Causes	29	27.94
Unknown	5	
All Deaths (SMR)	90	77.32 (116)

<sup>a</sup>Based on 7682.6 person-years.

<sup>b</sup> $p < 0.01$

## RESULTS

As shown in Table 2, a total of 90 deaths occurred among all talc workers from January 1, 1940 through December 31, 1975, as contrasted with 77.32 expected deaths determined from U.S. vital statistics patterns. The distribution of these deaths was such that the only statistically significant excess of mortality in the total cohort occurred in the non-malignant



respiratory disease category. This excess, 11 observed versus 1.79 expected, was specific for other non-malignant respiratory disease, excluding influenza and pneumonia (ONMRD).

A more detailed analysis of cause-specific mortality by working groups is shown in Table 3.<sup>5</sup> The mortality patterns observed in this table show that the excess of total non-malignant respiratory disease mortality, and more specifically ONMRD mortality, occurs primarily among those in the milling group (ONMRD: 7 observed versus 0.89 expected).

A significant increase in respiratory cancer mortality was observed only among miners (5 observed versus 1.15 expected). No difference of consequence was noted in the other group.

Vermont's death rates for non-malignant respiratory disease and respiratory cancer are greater than corresponding rates for the entire U.S. Vermont death data were only available back to 1949. Consequently, the person-years of observation from 1950 through 1975, calculated in the life table analyses described above, were applied to death rates of the United States and Vermont to obtain expected deaths for the study population during that time period. The patterns of statistically significant excess mortality were maintained in this comparison. The expected numbers of deaths for Vermont and the U.S. for ONMRD in millers are 1.33 and 0.86 respectively, versus 7 deaths observed ( $p < 0.01$  for both). The number of respiratory cancer deaths expected in the miners was 1.22 and 1.09 versus 5 deaths observed ( $p < 0.05$  and  $p < 0.01$ , respectively).

If the excess observed of non-malignant respiratory disease deaths in millers was a result of talc exposure, some confirmation of this relationship could be obtained by examining chest radiographs of these workers.

The Vermont Health Department supplied NIOSH with the readable radiographs for 8 of the 11 men who died of non-malignant respiratory disease. Of these eight with readable radiographs, six (75 percent) had radiographic readings of 2/1 or greater, indicating pneumoconiosis. All of these were small rounded opacities, the type usually observed with a non-fibrous exposure, and were generally distributed throughout the lungs. Two of the 11 ONMRD had prior dust exposure. When these two were excluded, six readable radiographs remain. Of these, 83.3 percent (5) were read as 2/1 or greater. Note should be made that these radiographs were taken while the workers were "relatively" healthy, that is, healthy enough to be actively employed.

Furthermore, this information was supplemented by qualitative radiograph readings<sup>6</sup> recorded by the Vermont Health Department for each annual survey. No discrepancies were found when these were compared to the readings discussed above. The Health Department information included readings for the three deaths for whom radiographs were either missing or unreadable. For the two cases with unreadable radiographs, earlier readings were available. All three cases had radiographic evidence of pneumo-

<sup>5</sup>These data do not tally with those listed in Table 2 due to the overlap caused by the definitions of "miner" and "miller."

<sup>6</sup>UICC/Cincinnati ratings were not used.

## MORTALITY PATTERNS OF NON-ASBESTIFORM TALC

279

coniosis, according to the Health Department's physician at the time the radiograph was taken. With this information incorporated into the tally, a total of nine of the eleven had radiographic readings consistent with pneumoconiosis.

**TABLE 3.** Number of Observed and Expected Deaths by Cause Among Vermont Talc Miners and Millers Employed One Year or More According to Work Area, 1940 Through 1975

Cause of Death (ICD No., 7th Revision)	Millers <sup>a</sup>		Miners <sup>b</sup>	
	Observed	Expected US	Observed	Expected US
Heart Disease (400-443)	16	15.77	9	11.24
All Malignant Neoplasms (140-199)	5	6.28	7	4.18
Respiratory (160-164)	2	1.96	5 <sup>c</sup>	1.15
Total Non-Malignant Respiratory Disease (470-527)	7 <sup>d</sup>	1.72	2	1.23
Influenza and Pneumonia (480-493)	0	.83	0	.67
Other Non-Malignant Respiratory Diseases (470-475, 500-527)	7 <sup>d</sup>	.89	2	.56
Other Known Causes	15	13.38	12	9.93
Unknown	1		4	
All Deaths (SMR)	44	37.15 (118)	34	26.58 (128)

<sup>a</sup> Based on 4128.5 person years.

<sup>b</sup> Based on 2865.4 person-years.

<sup>c</sup>  $p < 0.05$

<sup>d</sup>  $p < 0.01$

## ASSESSMENT OF OCCUPATIONAL EXPOSURES

Analyses of both airborne dust samples and talc bulk samples showed talcs from all locations in the mines and mills studied to be similar in composition. No asbestos was detected in any of the samples analyzed by either x-ray diffraction or analytical electron microscopy. Levels of free silica in talc bulk samples were below 0.25 percent for nearly all samples, and only in occasional air samples was free silica detectable. Talc shards and ribbons were seen in talc bulk and airborne dust samples. In addition to the mineral "talc," other minerals present in these ores in significant quantities include magnesite, chlorite, and dolomite in addition to traces of calcite, biotite, ankerite, and phlogopite.<sup>7</sup>

<sup>7</sup> Analyses presented in Boundy, M.: Occupational Exposures to Non-Asbestiform Talc in Vermont. Presented at Conference on Occupational Exposures to Fibrous and Particulate Dust and Their Extension into the Environment, Washington, D.C., December 6, 1977.



To determine potential differences in the talcs mined and milled by the company (in the third geographic location) no longer in operation, seven samples of talcs were obtained and analyzed by the same techniques mentioned above. These samples were found to be free of asbestos contamination and to have a mineral composition within the range of samples from currently producing operations. The one remaining company (also no longer in operation) was located in the same geographic area as two of the currently operating companies.

The historic data on the studied facilities, obtained from the Vermont Health Department, were not sufficient to calculate cumulative exposure histories for miners and millers. However, they are sufficient to demonstrate that it was not uncommon for past exposure levels to both miners and millers to far exceed the present Occupational Safety and Health Administration (OSHA) and the Mining Enforcement and Safety Administration (MESA) standard of 20 mppcf for nonfibrous talc (<1 percent free  $\text{SiO}_2$ ).

The talc in one of the closed mines is reported to have had "cobblestones" of serpentine rock which were highly tremolitic. In the mining of this talc, these "cobblestones" were avoided and/or discarded. Therefore, miners may have been exposed to tremolite, but it is unlikely that the millers from this company were.

Radon daughter levels in Vermont talc mines have been determined by MESA. Mean levels ranged from trace quantities to 0.12 working levels. Single measurements as high as 1.0 working levels have been measured in these mines.

NIOSH is currently attempting to identify any possibly confounding workplace exposures that may have occurred prior to or after employment in the Vermont talc industry, or those who died from malignant or non-malignant respiratory disease. Prior exposures have been identified to some extent by Vermont Health Department Records.

## DISCUSSION

The finding of excessive respiratory disease deaths among talc workers requires an evaluation of selection bias resulting from application of the criteria for inclusion in the study population. Bias may exist from selection into employment in this industry and subsequent radiographic examination as talc workers. During the early years of the program, radiographic examination was not done annually. There was no survey of talc workers for six of the first twelve years. During this time, the likelihood of missing workers with brief exposure was greater, especially in the period from 1944 through 1947, when no examinations were done. The bias associated with radiographic examination appears small, as the probability of examination increased with increasing length of employment. As the data were examined by latency and exposure categories, this bias was accounted for in the analyses. The Health Department, in the mid 1960's, did attempt to document those missing in their surveys. Although the completeness of this documentation is unknown, the following information resulted: Of the 178 workers identified during this check, approximately 27 percent worked

more than one year, but less than 3 percent worked more than five years. This supports the theory that those missed by the surveys were, for the most part, short-term workers.

To examine the effect of potential selection bias for persons with a predisposition toward respiratory disease, analyses of ONMRD mortality risk were made according to latency, that is, the time interval since onset of initial employment in the Vermont talc operations. The mortality patterns in millers demonstrate an observable excess after 15 years of employment (2 observed versus 0.31 expected,  $p > 0.05$ ) and a statistically significant risk after 30 years (5 observed versus 0.41 expected,  $p < 0.01$ ). This lack of an excess prior to 15 years and an increasing excess beginning after 15 years suggests that there was no selection bias toward less healthy workers; the data were consistent with other data comparing working populations with the general population. This phenomenon is known as the "healthy worker effect" (Bayliss et al., 1976; McMichael 1975). Those who are employed have lower death rates (are generally more healthy) than the general population, which includes invalid and institutionalized people. This healthy worker effect is more prominent in the years immediately after the workers are hired (Waxweiler, 1976).

Since pre-employment health screening was not past practice, it is unlikely that selective job placement (mine versus mill) occurred due to health status, and thus such selection could not explain the different trends observed.

The role of prior employment in other dusty industries can be reasonably excluded in the etiology of this non-malignant respiratory disease death risk. Only two workers who died from ONMRD had reported dust exposure prior to working in talc industry. When these two cases are excluded from analyses, the pattern of an excessive risk of ONMRD mortality in millers persists (7 observed versus 0.89 expected,  $p < 0.01$ ).

If there is truly an association of the statistically significant excess of ONMRD deaths with talc exposure, one would expect a confirmation of this with an examination of the most recent chest radiographs taken by the Vermont Department of Health as part of its annual surveillance of workers in the dusty trades. This association was supported by the readings as reported in the results section of this paper.

Insufficient historic data are available to estimate cumulative lifetime exposures for members of this cohort; however, available data show past dust exposures in the mines and mills to be higher than the present OSHA and MESA exposure standard of 20 mppcf. It is probable that cumulative dust exposures for millers over their working lifetimes are higher than those of miners, as mine operations are more sporadic in nature than are mill operations (eg. intermittent operations, such as drilling). Although there may be other possible factors, the relative differences noted in observed versus expected non-malignant respiratory disease deaths in the mining and milling populations are consistent with a talc exposure etiology. At this time, the data for the mines are extremely limited, too limited to make scientific judgment as to the presence or absence of an excess non-malignant respiratory disease death risk.

A majority of those workers who died of non-malignant respiratory disease or respiratory cancer did smoke cigarettes at some time during their lives. Unfortunately, no data on the smoking habits of the study population and no precise data on the comparison populations are available. However, it seems unlikely, due to the magnitude of the difference, that the observed excess of non-malignant respiratory disease deaths is associated only with unusual smoking patterns and then *only* among talc millers. It is equally unlikely that the excess risk of lung cancer found in the miners is associated with unusual smoking patterns *only* in that group. Because of the limited smoking data, no conclusions may be drawn from these mortality data concerning the possible additive or synergistic effects of smoking and talc dust exposure.

### CONCLUSIONS

The present study demonstrated excessive mortality due to non-malignant respiratory disease among talc millers exposed to a talc free both of asbestiform minerals and significant quantities of free silica. Selective bias and other causative factors do not adequately explain the observed excesses, although the possibility does exist of an interactive effect between cigarette smoking and talc exposure. Radiographic evidence further supports the role of talc exposure, free of asbestos and free silica, in the etiology of the increased risk of non-malignant respiratory disease among these talc millers.

The cumulative talc exposure levels associated with this excess are unknown, due to the sporadic nature of early sampling of the mills and mines. However, the past samples are sufficient to demonstrate that it was not uncommon for past exposure levels to far exceed the present Occupational Safety and Health Administration and the Mining Enforcement and Safety Administration standard of 20 mppcf for non-fibrous talc (<1 percent free  $\text{SiO}_2$ ).

Mortality patterns observed are reflective of these early exposure levels. No judgment can be made, from this study, concerning the effects of present-day exposures in this industry.

The fact that excess lung cancer mortality was observed for miners and not millers, despite probable higher dust exposure in mill operations, suggests that additional etiologic agent(s), either alone or in combination with talc dust, affect mine workers. The possible role of radon daughter exposures for this cancer mortality risk cannot be eliminated.

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Radiographs were read by Benjamin Felson, M.D. of the Department of Radiology, Cincinnati General Hospital.

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